

**§ 522.1890 Sterile prednisone suspension.**

(a) [Reserved]

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 to 40 milligrams of prednisone.(2) *Sponsor.* See 000061 in § 510.600(c) of this chapter.(3) *Conditions of use*—(i) *Amount.* Administer intramuscularly as follows:(a) *Horses.* 100 to 400 milligrams, repeating if necessary. If no response is observed after 3 to 4 days of therapy, reevaluate diagnosis.<sup>1</sup>(b) *Dogs and cats.* 0.25 to 1.0 milligram per pound of body weight for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.<sup>1</sup>(ii) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.<sup>1</sup>(iii) *Limitations.*<sup>1</sup> Do not use in viral infections. Except in emergency therapy, do not use in animals with tuberculosis, chronic nephritis, or Cushing's disease. With infections, use appropriate antibacterial therapy with and for at least 3 days after discontinuance of use and disappearance of all signs of infection. Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 13446, Feb. 29, 1980, as amended at 50 FR 6160, Feb. 14, 1985; 52 FR 7832, Mar. 13, 1987]

**§ 522.1920 Prochlorperazine, isopropamide for injection.**(a) *Specifications.* Prochlorperazine, isopropamide for injection, veterinary, contains in each milliliter, 6 milli-

grams of prochlorperazine edisylate (equivalent to 4 milligrams prochlorperazine), and 0.38 milligrams of isopropamide iodide (equivalent to 0.28 milligrams of isopropamide) in buffered aqueous solution.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.(c) *Conditions of use.* (1) The drug is used in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(2) Dosage is administered by subcutaneous injection twice daily as follows:

| Weight of animal in pounds | Dosage in Milliliters |
|----------------------------|-----------------------|
| Up to 4 .....              | 0.25                  |
| 5 to 14 .....              | 0.5-1                 |
| 15 to 30 .....             | 2-3                   |
| 30 to 45 .....             | 3-4                   |
| 45 to 60 .....             | 4-5                   |
| Over 60 .....              | 6                     |

Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

**§ 522.1940 Progesterone and estradiol benzoate in combination.**

(a) [Reserved]

(b) *Sponsor.* See 000856 for use as provided in paragraphs (d)(1) and (d)(2) of this section; see 021641 for use as provided in paragraphs (d)(1) and (d)(2)(i) through (d)(2)(iii)(A) of this section.(c) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.(d) *Conditions of use.* It is used for implantation in animals as follows:(1) *Suckling beef calves*—(i) *Amount.* 100 milligrams of progesterone and 10 milligrams of estradiol benzoate per dose.(ii) *Indications for use.* Increased rate of weight gain.(iii) *Limitations.* For use in suckling beef calves (at least 45 days of age) up to 400 pounds of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction.<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Steers*—(i) *Amount*. 200 milligrams of progesterone and 20 milligrams of estradiol benzoate per dose.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations*. (A) For animals weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal.

(B) For additional improvement in rate of weight gain in steers fed in confinement for slaughter, reimplant at approximately day 70.

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 48659, Oct. 20, 1983; 49 FR 13873, Apr. 9, 1984; 51 FR 21746, June 16, 1986; 52 FR 45312, Nov. 27, 1987; 53 FR 7406, Feb. 21, 1989; 55 FR 13769, Apr. 12, 1990; 59 FR 49808, Sept. 30, 1994; 61 FR 5507, Feb. 13, 1996; 62 FR 8372, Feb. 25, 1997]

**§ 522.1962 Promazine hydrochloride injection.**

(a) *Specifications*. Each milliliter of sterile aqueous solution contains 50 milligrams of promazine hydrochloride.

(b) *Sponsor*. In § 510.600(c) of this chapter, see No. 000008 for conditions of use as in paragraph (c)(1)(i) of this section; see No. 000856 for conditions of use as in paragraph (c)(1)(ii) of this section; see No. 000864 for conditions of use as in paragraph (c)(1)(iii) of this section.

(c) *Conditions of use*. (1)(i) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats 1 to 3 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer or preanesthetic.<sup>1</sup>

(ii) To horses either intramuscularly or intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, and to dogs and cats at 1 to 2 milligrams per pound of body weight, every 4 to 6 hours as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic in dogs and

cats prior to worming, or to prevent motion sickness in dogs.<sup>1</sup>

(iii) To horses intravenously at a dosage of 0.2 to 0.5 milligram per pound of body weight, as a tranquilizer and preanesthetic, as required.<sup>1</sup>

(2) Not for use in conjunction with organophosphates because their toxicity may be potentiated, nor with procaine hydrochloride as its activity may be increased.<sup>1</sup>

(3) Not for use in horses intended for food.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[46 FR 18962, Mar. 27, 1981]

**§ 522.2002 Propiopromazine hydrochloride injection.**

(a) *Chemical name*. 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications*. Propiopromazine hydrochloride injection contains 5 or 10 milligrams of the drug in each milliliter of sterile aqueous solution.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) It is administered either intravenously or intramuscularly to dogs and cats for tranquilization at a dosage level of 0.05–0.5 milligram per pound of body weight and is also administered intravenously to dogs and cats as a preanesthetic at a dosage level of 0.25 milligram per pound of body weight.

(2) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride since phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5507, Feb. 13, 1996]

**§ 522.2005 Propofol injection.**

(a) *Specifications*. The drug is a sterile, nonpyrogenic, oil-in-water emulsion containing 10 milligrams of propofol per milliliter.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

<sup>1</sup>These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.